DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Toshiba Medical Systems Corporation
% Mr. Paul Biggins
U.S. Agent/Director Regulatory Affairs
Toshiba America Medical System, Inc.
2441 Michelle Drive
TUSTIN CA 92780

January 29, 2015

Re: K143281
Trade/Device Name: Ultimax-i
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: November 14, 2014
Received: November 17, 2014

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143281

Device Name
Ultimax-i

Indications for Use *(Describe)*
The Ultimax-i multipurpose digital X-ray system is designed for gastrointestinal studies, vascular studies, general radiography, and fluoroscopy.
The Ultimax-i system has medical applications ranging from but not limited to: contrast enhanced studies, support of endoscopic studies, nonvascular contrast-enhanced studies, nonvascular IVR, vascular contrast-enhanced studies, support of vascular IVR, and general radiography.
Note: This system is not intended for cardiovascular contrast studies or interventional radiology procedures for the cardiac or cerebral blood vessels. This system is not intended for mammography studies in the US.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. CLASSIFICATION and DEVICE NAME:

Classification Name:	**Image Intensified Fluoroscopic X-ray System**
Regulation Number:	**21 CFR 892.1650 (Class II)**
Product Code	**OWB-Interventional Fluoroscopic X-ray System (Primary)** **JAA – Image Intensified Fluoroscopic X-ray System (Secondary)**
Trade Proprietary Name:	**Ultimax-i**
Model Number:	**DREX-UI80**

2. ESTABLISHMENT REGISTRATION: 9614698

3. CONTACT PERSON, U.S. AGENT and ADDRESS:

Contact Person/U.S. Agent:
Paul Biggins
Director, Regulatory Affairs
(714) 730-5000
Fax (714) 730-1310
pbiggins@tams.com

Establishment Name and Address:
Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, Ca. 92780

4. MANUFACTURING SITE

Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan
Contact: Akinori Hatanaka

5. Date OF SUBMISSION:

November 13, 2014

6. PERFORMANCE STANDARD:

21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

7. PREDICATE DEVICE:

Toshiba, KALARE (DREX-KL80) , K133553

Siemens Medical Systems, Artis Zee Multi-purpose K122664

8. REASON FOR SUBMISSION:

New device

9. SUBMISSION TYPE:

Traditional 510(k)

10. DEVICE DESCRIPTION:

This device is a fixed c-arm fluoroscopic device intended to provide radiographic and fluoroscopic images in a variety of studies. The unit consists of a c-arm with x-ray tube, beam limiter and digital flat panel detector (FPD); a patient table that can tilt in both directions, an 80kW x-ray generator, an image processor and both remote and table side control.

11. SUMMARY OF INTENDED USES:

The Ultimax-i multipurpose digital X-ray system is designed for gastrointestinal studies, vascular studies, general radiography, and fluoroscopy.

The Ultimax-i system has medical applications ranging from but not limited to: contrast-enhanced studies, support of endoscopic studies, nonvascular contrast-enhanced studies, nonvascular IVR, vascular contrast-enhanced studies, support of vascular IVR, and general radiography.

Note: This system is not intended for cardiovascular contrast studies or interventional radiology procedures for the cardiac or cerebral blood vessels.

12. SUMMARY OF CHANGE(S)

The Ultimax has the same Image processor and employs the base software of the KALARE. Introduction of changes to the table and FPD mounting assembly have been implemented to provide an expansion to the type of studies performed on the Toshiba KARALE system. These changes are a new table and c-arm configuration for the mounting of the image receptor (digital flat panel detector) and the x-ray source.

This device is similar to the Siemens Artis Zee Multi-purpose as follows:

- Similarity in intended uses
- Both designs are centered around an integrated C-arm and table configuration.
- Has similar movement of both table and FPD/tube assembly.
- Both systems are floor mounted c-arm interventional x-ray systems

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the KALARE, K133553, marketed by Toshiba America Medical Systems. Both systems have the same intended use as general fluoroscopy/radiographic systems. Ultimax-i includes modifications to the cleared device which adds functionality to the table and FPD movement, base software and

manufacturing process remain unchanged from the cleared device. Comparison of image performance criteria demonstrate that the two devices perform in a similar manner. Clinical data was used to further demonstrate the effectiveness of the Ultimax-i system.

This device is substantially equivalent to the Siemens Artis Zee Multi-purpose room in that the hardware configurations and thus intended uses are the similar.

14. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 standards, its collateral standards and particular standards; IEC60601-2-54, IEC60601-2-43 and IEC 60601-2-28. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

15. TESTING

Testing of the modified system was conducted in accordance with the applicable standards published by the International Electromechanical Commission (IEC) for Medical Devices and XR Systems. Bench testing was done to confirm that the installation of the detector met the stated specifications of the component manufacturer. Additional testing was done to compare the performance between the predicate device (KALARE) and the modified device that included testing directed at image quality, artifacts and motion/dynamic capabilities. The sponsor has included clinical images in this submission to support the efficacy of the new device. Additionally, in support of this conclusion the detector component has been the subject of other 510k Premarket Notifications where the clinical aspects of the component have been addressed.

16. CONCLUSION

The Ultimax-i has the same intended use as the predicate devices. Safety and effectiveness have been verified via risk management and the application of design controls to the modifications.